From: Steve Spaulding
To: Hollis, Linda

Cc: Greene, Cheryl; Bryceland, Andrew; Burnett, Gina; Parker, James

Subject: RE: Livengood Feeds Use of Diacon-D Methoprene in Animal Feeds

**Date:** Wednesday, March 16, 2022 2:08:32 PM

Hi Linda,

Is there a good time for you for a call? I am free all day tomorrow and Friday.

\*\*\*\*\*\*\*\*\*\*\*\*

Steven R. Spaulding
Vice President of Regulatory Affairs
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dba Central Life Sciences
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sspaulding@central.com

From: Hollis, Linda <Hollis.Linda@epa.gov> Sent: Monday, March 14, 2022 7:24 PM

To: Steve Spaulding <SSpaulding@central.com>

**Cc:** Greene, Cheryl <Greene.Cheryl@epa.gov>; Bryceland, Andrew <Bryceland.Andrew@epa.gov>;

Burnett, Gina <Burnett.Gina@epa.gov>; Parker, James <Parker.James@epa.gov>

Subject: RE: Livengood Feeds Use of Diacon-D Methoprene in Animal Feeds

♠ External

Hello Steve-

I apologize for not responding. I am really trying to wrap my head around the issue. I believe that the label in question that my team reviewed in response to the state inquiry was from 2011. I also believe that the issue related to use of the product in medicated feed and others. So I am really not sure what is the issue at this point as we have not received any further inquiries from the state. I do see that the label that was conditionally approved in 2012 cites conditions. We would need to look in our files to see if those conditions have been met. Generally, once conditions have been met, a newly stamped label is approved.

What is the issue here? Stored grains? I see issues with the 2012 approved language. In hindsight, from a glance, it seems odd.

Perhaps a meeting would help me and my team get to the core of the matter.

With regard to my interpretation of 152.25, I cannot respond via this email as to whether I agree or not, but will discuss the issue with my team as well as counsel as we normally do with all interpretations.

I am in the office this week and will make the time. What is your availability?

Regards,

Linda Hollis

**From:** Steve Spaulding < <u>SSpaulding@central.com</u>>

**Sent:** Monday, March 14, 2022 4:10 PM **To:** Hollis, Linda < Hollis.Linda@epa.gov>

**Subject:** RE: Livengood Feeds Use of Diacon-D Methoprene in Animal Feeds

#### Linda.

I am following up on the use of Diacon-D to treat bagged livestock feed to control stored grain pests again since we have received yet another call from a customer about this use in Texas. I talked to Cheryl today and she said there was nothing she could do about it since enforcement issues were handled by you. I received additional clarification from Texas about this issue. Evidently, their concern is about the statement in the attached Position Paper. "Our interpretation is that the treated article exemption applies to animal feed....". They would like EPA documentation that supports such use and the interpretation by us or someone within EPA to discuss the 40 CFR Part 152.25 Exemption. I think the fact that you approved the following statement on the attached stamped approved label indicates that EPA agrees with this interpretation of the treated article exemption:

"Applications of RF2047 DP to finished animal feeds, birdseed or other finished products <u>DO NOT</u> require package labeling since the application is made to control pests in the package and no other claims are made on the final package".

Furthermore, use of this product is approved for mixing into animal feeds as described in the section of the attached label "Directions for Mixing into Animal Feeds".

I need your help to resolve this issue which is disrupting our business for a highly desirable product to control stored product pests in livestock feed. You can reply to me that you agree with the interpretation of 40 CFR Part 152.25 and the use of the product according to the approved label and I can take it up with Ben Jones or reply directly to Ben Jones, Office of the Texas State Chemist, at <a href="blig@otsc.tamu.edu">blig@otsc.tamu.edu</a> or by phone at (979) 845-1121. All I am really asking is that you confirm the use of this product as you already approved on the label. We discussed this use several times back in 2011 leading up to the label amendment to clarify the directions for use.

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From: Hollis, Linda < Hollis.Linda@epa.gov > Sent: Friday, February 18, 2022 2:57 PM

**To:** Steve Spaulding < <a href="mailto:SSpaulding@central.com">SSpaulding@central.com</a>>

**Cc:** Rust, Mary < <a href="mailto:Rust.Mary@epa.gov">Rust.Mary@epa.gov</a>>

**Subject:** Re: Livengood Feeds Use of Diacon-D Methoprene in Animal Feeds



# Hello Steve,

I was on leave for much of December. My team received a related inquiry through the BPPD questions. My team responded to the the inquiry, which I believe, was the state. I do not have that response at my fingertips at the moment.

Sent from my iPhone

On Feb 18, 2022, at 3:51 PM, Steve Spaulding < <u>SSpaulding@central.com</u>> wrote:

# Linda,

I sent you the email below back in December and never heard back from you. The issue has come up again and I need to resolve this once and for all. Can you please review the email below and let me know if you agree that Diacon-D can be used to treat the contents of bagged animal feed to control stored product pests. We can set up a call to discuss if you like.

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From: Steve Spaulding

Sent: Tuesday, December 21, 2021 4:14 PM

**To:** Linda Hollis < <a href="mailto:hollis.linda@epa.gov">hollis.linda@epa.gov</a>>; <a href="mailto:rust.mary@epa.gov">rust.mary@epa.gov</a>

**Subject:** Livengood Feeds Use of Diacon-D Methoprene in Animal Feeds

#### Good Afternoon Linda & Mary,

I am contacting you about an issue I was recently made aware of in Texas by Mr. Ben Jones concerning the stop sale placed by the Office of the Texas State Chemist on Livengood poultry feed treated with Diacon D (EPA Reg. No. 2724-788) to control stored product pests. He requested EPA documentation that

supports the use of this product to treat animal feed. I explained to him that we had discussions with BPPD and you agreed this use could be added to the label by amendment. I sent him the attached EPA-Stamped Approved Label (marked with changes) dated December 13, 2011 since that was the first label I located in our files showing that you agreed this was an acceptable use and the attached commercial label for Diacon D IGR and thought the issue was resolved. He contacted me again last Friday to let me know that he contacted Mary Rust of BPPD for an opinion and she elevated the issue to the BPPD Branch Chief. Evidently, when comparing the marked label with changes with the commercial label, you noted that many of the changes had not been made and you felt this product was improperly labeled and would require an amendment to correct the problem.

I went through our files to see where the disconnect was and discovered the following chronology of events.

- 1. On November 18, 2020, Wellmark submitted an amendment to clarify the directions for use to treat animal feeds (submission attached)
- 2. On December 13, 2011, BPPD approved the amendment with changes (label attached)
- 3. On December 21, 2011, I sent an email to Cheryl Greene after I had a telephone discussion with Linda Hollis about concerns we had with the stamped approved label marked with changes. I identified concerns we had with (1) the requirements to add a Worker Protection Box since this was not an agricultural use, (2) requested a clean copy of the label, (3) expressed concerns about the use of "stored" and "commodity" and "broad range of insects throughout the label.
- 4. On January 12, 2012, we received another stamped approved clean copy of the label (label attached). Evidently, the concerns expressed in the December 21, 2011 email were taken into account by BPPD and these points were not included on this version of the label. This most recent version of the approved label is what our commercial label is based on and is the version that appears in PPLS. I think the disconnect occurred because I sent Mr. Jones the wrong version of the approved label.

My conclusion is that Diacon D is properly labeled for treating animal feed and is in compliance with the most recent EPA approved label. Could you please confirm that you agree with my conclusion and I can contact Mr. Jones accordingly and you can contact him yourself to close the issue so that the feed can be released from the stop sale. If you do not agree, I would like to have a call to discuss.

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